

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

**MARJORIE FERRELL, et al.,**

**Plaintiffs,**

**V.**

**WYETH-AYERST LABORATORIES, INC.,  
et al.,**

## Defendants.

**Civil Action No. C-1-01-447**

**Judge Sandra S. Beckwith**  
**Magistrate Judge Timothy S. Hogan**

## DEFENDANTS' ANSWER

Defendants Wyeth Pharmaceuticals Inc. (formerly Wyeth-Ayerst Laboratories Inc.) and Wyeth (formerly American Home Products Corporation), collectively referred to as “Wyeth,” by their undersigned counsel, hereby respond to the Corrected Consolidated Amended Class Action Complaint (the “Complaint”) dated January 2, 2002, as follows:

1. Wyeth admits that plaintiffs purport to bring a class action on behalf of end-payors who purchased Premarin. Wyeth admits that Premarin is the brand name of the conjugated estrogens product manufactured and sold by Wyeth.

2. Wyeth admits that Premarin is indicated in the treatment of moderate to severe vasomotor symptoms associated with menopause, as well as other indications. Wyeth admits the allegations contained in the third sentence of paragraph 2. Wyeth denies the remaining allegations in paragraph 2 of the Complaint.

3. Wyeth denies the allegations in paragraph 3 of the Complaint.

4. Wyeth denies the allegations in paragraph 4 of the Complaint.
5. Wyeth denies the allegations in paragraph 5 of the Complaint.
6. Wyeth admits that Count I of the Complaint contains the allegations described and is brought by plaintiffs purportedly on behalf of the persons described, but denies the truth of such allegations.
7. Wyeth admits that Count II of the Complaint contains the allegations described and is brought by plaintiffs purportedly on behalf of the persons described, but denies the truth of such allegations.
8. Wyeth admits that Count III of the Complaint contains the allegations described and is brought by plaintiffs purportedly on behalf of the persons described, but denies the truth of such allegations.
9. Wyeth admits that Count IV of the Complaint contains the allegations described and is brought by plaintiffs purportedly on behalf of the persons described, but denies the truth of such allegations and denies that plaintiffs are entitled to any of the relief sought.
10. The allegations contained in paragraph 10 of the Complaint purport to state a legal conclusion and therefore no response is required. Wyeth denies plaintiffs are entitled to the relief sought.
11. The allegations in paragraph 11 purport to state a legal conclusion and therefore no response is required.
12. The allegations in paragraph 12 purport to state a legal conclusion and therefore no response is required.

13. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 13 of the Complaint. Wyeth denies the remaining allegations in paragraph 13 of the Complaint.

14. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 14 of the Complaint. Wyeth denies the remaining allegations in paragraph 14 of the Complaint.

15. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 15 of the Complaint. Wyeth denies the remaining allegations in paragraph 15 of the Complaint.

16. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 16 of the Complaint. Wyeth denies the remaining allegations in paragraph 16 of the Complaint.

17. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 17 of the Complaint. Wyeth denies the remaining allegations in paragraph 17 of the Complaint.

18. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 18 of the Complaint. Wyeth denies the remaining allegations in paragraph 18 of the Complaint.

19. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 19 of the Complaint. Wyeth denies the remaining allegations in paragraph 19 of the Complaint.

20. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 20 of the Complaint.

21. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of the Complaint.

22. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint.

23. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Complaint.

24–25. Wyeth Pharmaceuticals Inc. (formerly Wyeth-Ayerst Laboratories Inc.), a Delaware corporation, is a wholly owned subsidiary of Wyeth (formerly American Home Products Corporation), which is also a Delaware corporation. Defendants manufacture and sell a conjugated estrogens product under the trademark Premarin. Sales of Wyeth's women's health care products in the aggregate, and the Premarin family of products (Premarin, Prempro and Premphase) individually, accounted for more than 10% of consolidated net revenue in 2000, 1999, and 1998. Wyeth denies the remaining allegations in paragraphs 24 and 25 of the Complaint.

26. Wyeth denies the allegations in paragraph 26 of the Complaint.

27. Wyeth denies the allegations in paragraph 27 of the Complaint.

28. Wyeth admits that plaintiffs purport to bring this case as a class action, but denies that a class action should be certified in this case.

29. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29 of the Complaint.

30. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence in paragraph 30 of the Complaint. Wyeth denies the remaining allegation in paragraph 30 of the Complaint.

31. Wyeth denies the allegations in paragraph 31 of the Complaint.

32. Wyeth denies the allegations in paragraph 32 of the Complaint.

33. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 33 of the Complaint.

34. Wyeth denies the allegations in paragraph 34 of the Complaint.

35. Wyeth denies the allegations in paragraph 35 of the Complaint.

36. Wyeth denies the allegations in paragraph 36 of the Complaint.

37. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 37 of the Complaint, but Wyeth denies that this action can be maintained as a class action.

38. Wyeth admits that menopause is a normal part of a woman's aging process, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 38 of the Complaint.

39. Wyeth denies the allegations contained in the first sentence of paragraph 39 of the Complaint. Wyeth admits the allegations contained in the second sentence in paragraph 39 of the Complaint. Wyeth lacks information sufficient to form a belief as to the truth of the remaining allegations in paragraph 39 of the Complaint.

40. Wyeth admits that the FDA approved Premarin under the Federal Food, Drug, and Cosmetics Act, but denies the remaining allegations contained in the first sentence of paragraph 40. Wyeth admits that it manufactures and markets Premarin, but denies the remaining allegations contained in the second sentence of paragraph 40. Wyeth further states that a predecessor entity began manufacturing and marketing Premarin in 1942. Wyeth admits that, in 1986, the FDA confirmed the acceptability of

Premarin's indication for the prevention and treatment of osteoporosis, but denies the remaining allegations contained in the third sentence of paragraph 40 of the Complaint.

41. Wyeth admits the allegations in the first sentence of paragraph 41. Wyeth denies the remaining allegations in paragraph 41 of the Complaint.

42. Wyeth admits the allegations in first sentence of paragraph 42. Wyeth admits the USP designation in the Premarin name signifies that that it complies with the definition of conjugated estrogens contained in the United States Pharmacopeia ("USP"), which publishes the United States' official compendium of pharmaceuticals. Wyeth denies the remaining allegation in paragraph 42 of the Complaint.

43. Wyeth admits that it has had annual sales of Premarin exceeding \$800 million. Wyeth denies the remaining allegations in paragraph 43 of the Complaint.

44. Wyeth admits the allegations contained in the first sentence of paragraph 44. Wyeth admits that Cenestin has been classified by the FDA as "synthetic conjugated estrogens, A", and that some, but not all, Cenestin dosage strengths are indicated for the treatment of moderate-to-severe vasomotor symptoms associated with menopause in women, and that Duramed received FDA's approval to market Cenestin in March 1999. Wyeth denies or lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 44 of the Complaint.

45. Wyeth admits the allegations contained in the first and third sentences in paragraph 45. Wyeth denies the remaining allegations in paragraph 45 of the Complaint.

46. Wyeth admits that in or about 1972, the FDA reviewed a number of estrogen products, including Premarin, and published a Federal Register Notice that these drugs have been shown to be effective in the treatment of menopausal symptoms. Wyeth

lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 46 of the Complaint.

47. Wyeth admits that delta <sup>8,9</sup>-DHES is present in Premarin, but Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 47 of the Complaint.

48. Wyeth denies the allegations in paragraph 48 of the Complaint.

49. Wyeth denies the allegations in paragraph 49 of the Complaint.

50. Wyeth denies the allegations in paragraph 50 of the Complaint.

51. Wyeth denies the allegations in paragraph 51 of the Complaint.

52. Wyeth admits the allegations contained in the first sentence of paragraph 52. Wyeth admits that it issued a press release on March 25, 1999, but denies the remaining allegations in paragraph 52 of the Complaint.

53. Wyeth denies the allegations in paragraph 53 of the Complaint.

54. Wyeth denies the allegations in paragraph 54 of the Complaint.

55. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 55 of the Complaint.

56. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 56 of the Complaint

57. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 57 of the Complaint.

58. Wyeth denies the allegations in paragraph 58 of the Complaint.

59. Wyeth lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first, second, third and fourth sentences of

paragraph 59. Wyeth denies the allegations contained in the fifth sentence of paragraph 59 of the Complaint.

60. Wyeth admits that it has entered into some contracts with health plans and PBMs and that such contracts speak for themselves. Wyeth denies the remaining allegations in paragraph 60 of the Complaint.

61. Wyeth admits that it has entered into some contracts with health plans and PBMs and that such contracts speak for themselves. Wyeth denies the remaining allegations in paragraph 61 of the Complaint.

62. Wyeth admits that it has entered into some contracts with health plans and PBMs and that such contracts speak for themselves. Wyeth denies the remaining allegations in paragraph 62 of the Complaint.

63. Wyeth denies the allegations in paragraph 63 of the Complaint.

64. Wyeth denies the allegations in paragraph 64 of the Complaint.

65. Wyeth denies the allegations in paragraph 65 of the Complaint.

66. Wyeth denies the allegations in paragraph 66 of the Complaint.

67. Wyeth denies the allegations in paragraph 67 of the Complaint.

68. Wyeth denies the allegations in paragraph 68 of the Complaint.

69. For purposes of its response to paragraph 69, Wyeth incorporates by reference its responses to paragraphs 1-68 of the Complaint.

70. Wyeth denies the allegations in paragraph 70 of the Complaint.

71. Wyeth denies the allegations in paragraph 71 of the Complaint.

72. Wyeth denies the allegations in paragraph 72 of the Complaint.

73. For purposes of its response to paragraph 73, Wyeth incorporates by reference its responses to paragraphs 1-72 of the Complaint.

74. Wyeth denies the allegations in paragraph 74 of the Complaint.

75. Wyeth denies the allegations in paragraph 75 of the Complaint.

76. Wyeth denies the allegations in paragraph 76 of the Complaint.

77. Wyeth denies the allegations in paragraph 77 of the Complaint.

78. Wyeth denies the allegations in paragraph 78 of the Complaint.

79. For purposes of its response to paragraph 79, Wyeth incorporates by reference its responses to paragraphs 1-78 of the Complaint.

80. Wyeth denies the allegations in paragraph 80 of the Complaint.

81. Wyeth denies the allegations in paragraph 81 of the Complaint.

82. Wyeth admits that plaintiffs purport to seek damages and treble damages, but denies that plaintiffs and the classes they purport to represent are entitled to such relief.

83. Wyeth admits that plaintiffs purport to seek damages and treble damages, but denies that plaintiffs and the classes they purport to represent are entitled to such relief.

84. For purposes of its response to paragraph 84, Wyeth incorporates by reference its responses to paragraphs 1-83 of the Complaint.

85. Wyeth denies the allegations in paragraph 85 of the Complaint.

86. Wyeth denies the allegations in paragraph 86 of the Complaint.

87. Wyeth denies the allegations in paragraph 87 of the Complaint.

To the extent that any response is required to the Prayer for Relief in the Complaint, Wyeth denies each and every allegation contained therein.

Wyeth denies each and every allegation in the Complaint not specifically admitted above.

#### ADDITIONAL DEFENSES

Wyeth hereby asserts the following additional defenses, without assuming any burden of proof on such defenses that would otherwise rest on plaintiffs.

##### FIRST DEFENSE

The Complaint fails to state a claim against Wyeth upon which relief can be granted.

##### SECOND DEFENSE

Plaintiffs lack standing to assert some or all of their claims.

##### THIRD DEFENSE

Wyeth's conduct was not intended to have, did not have, and is not likely to have any adverse effect on competition in any relevant market.

##### FOURTH DEFENSE

Plaintiffs have not sustained antitrust injury.

##### FIFTH DEFENSE

Wyeth's conduct is not the actual or proximate cause of plaintiffs' alleged injuries.

##### SIXTH DEFENSE

Any adverse effects alleged by plaintiffs were the result of legitimate market forces, including, but not limited to: (a) Cenestin is an inferior product; (b) Cenestin lacks

osteoporosis and other key indications; (c) Cenestin was introduced with limited strengths; (d) Cenestin was introduced with limited clinical data; (e) Duramed's poor marketing strategy; (f) Duramed's poor pricing strategy; (g) lack of adequate sales and marketing support; (h) lack of physician demand; (i) purchasing programs of wholesalers and retailers; and/or (j) other causes that are independent of Wyeth's alleged conduct.

SEVENTH DEFENSE

Wyeth had legitimate business justifications for all of its conduct at issue in this matter.

EIGHTH DEFENSE

Wyeth's conduct at issue in this matter was procompetitive.

NINTH DEFENSE

Wyeth lacks market power in the relevant market.

TENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by laches, estoppel, waiver, and/or unclean hands.

ELEVENTH DEFENSE

Plaintiffs have failed to join indispensable parties.

TWELFTH DEFENSE

Plaintiffs have failed to state a claim for injunctive relief under 16 U.S.C. § 26 and under the equitable theory of unjust enrichment because plaintiffs have an adequate remedy at law.

THIRTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the damages sought are too speculative and too remote.

FOURTEENTH DEFENSE

This action may not properly be maintained as a class action because (a) the named plaintiffs will not fairly and adequately protect the interests of the putative classes; (b) common issues of law and fact, if any, do not predominate over individual issues; (c) a class action is not superior to other available methods for the fair and efficient adjudication of the controversy; (d) there are conflicts among the class members; and (e) other requirements of maintaining this action as a class action have not been met.

FIFTEENTH DEFENSE

To the extent that plaintiffs' claims are premised, in whole or in part, on Wyeth's activity involving, or is incidental to, petitioning of government, the claims are barred, in whole or in part, by the First Amendment to the Constitution of the United States, the constitutions of the states and by the *Noerr-Pennington* Doctrine.

Wyeth reserves the right to assert additional defenses at a later time.

Respectfully submitted,

s/Grant S. Cowan

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Dated: July 20, 2004

**CERTIFICATE OF SERVICE**

The undersigned, an attorney, hereby certifies that a copy of the foregoing has been served electronically this 20<sup>th</sup> day of July, 2004 on all Counsel of Record with the CM/ECF Registration and by regular U.S. mail, postage prepaid upon the following:

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